

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 20-1120V**

DARRELL WILLIAMS,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES

Respondent.

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Chief Special Master Corcoran

Filed: March 31, 2025

DECISION DISMISSING CASE¹

On September 2, 2020, Darrell Williams filed a petition for compensation under the National Vaccine Injury Compensation Program (the “Vaccine Program”).² Petitioner alleges that an influenza vaccine he received on October 5, 2018, caused “adverse effects,” including “symptoms of pain and abscesses.” *See generally* Petition (ECF No. 1). The vaccine he received was administered by a Kentucky mobile vaccination entity that was later determined to have exercised inadequate safety control over its vaccines, resulting in numerous vaccinated individuals experiencing comparable abscess injuries.

Respondent opposes Petitioner's claim, arguing that the Act's “severity” requirement cannot be met. After a careful review of the entirety of the parties’ submissions, I find there is not preponderant evidence that Petitioner’s abscess injury persisted for at least six months post-vaccination. *See* Section 11(c)(1)(D). Therefore, Petitioner’s claim is not eligible to proceed within the Vaccine Program, and it must be dismissed.

¹ Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public in its present form. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) (“Vaccine Act” or “the Act”). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Relevant Procedural History

This matter was initiated at the same time as a number of related petitions brought by similarly-situated claimants.³ Respondent raised an overarching objection to these claims – that they did not fall within the ambit of the Program due to third-party negligence that resulted in the subsequent abscess injuries. The parties consented to resolution of entitlement in one “test case,” the results of which could then be applied to the related cases. On April 25, 2024, I ruled in favor of the petitioner in the test case, finding that the administration of the influenza vaccine had caused him to experience a right shoulder skin abscess associated with a bacterial infection. *See Silvers v. Sec’y of Health & Hum. Servs.*, No. 20-1V, 2024 WL 2799285 (Fed. Cl. Spec. Mstr. Apr. 25, 2024).

On September 17, 2024, I held a telephonic status conference (under the auspices of the test case matter) to discuss resolution of the remaining cases. I proposed at that time that Respondent determine if entitlement could be conceded in light of my test case ruling, or if facts specific to the remaining cases required different treatment. On October 10, 2024, the parties filed a joint status report in the four remaining cases, announcing that Petitioner did not intend to file additional evidence relevant to the issue of six-month severity and requesting deadlines for Rule 4(c) reports. I subsequently ordered the parties to file Rule 4(c) Reports in the related matters by November 15, 2024.

On November 13, 2024, Respondent filed a Rule 4(c) Report in this action, arguing that Petitioner was not entitled to compensation because of his failure to satisfy the Act’s six-month severity requirement. (ECF No. 19). My preliminary review of the record suggested that this defense was meritorious, but I permitted Petitioner to file a brief showing cause why the petition should not be dismissed for inability to meet the severity requirement. Order to Show Cause, dated Nov. 14, 2024 (ECF No. 20). On December 31, 2024, Petitioner filed his response to the Order. Petitioner’s Brief (ECF No. 21) (“Br.”). On January 30, 2025, Respondent filed his opposition. Respondent’s Opposition (ECF No. 23) (“Opp.”). The matter is now ripe for decision.

II. Factual Background

Petitioner was born on July 20, 1957, and was 61 years old at the time of vaccination. Petition at 1. He received the flu vaccine on October 5, 2018, and it was administered by the same mobile vaccination entity discussed in *Silvers*. *Id.*

After learning in December 2018 from state authorities that vaccines received from the mobile entity might have resulted in abscess-like injuries, Mr. Williams sought medical treatment

³ See generally *Silvers v. Secretary of Health and Human Services* (No. 20-1V), *Stastny v. Secretary of Health and Human Services* (No. 20-22V), and *Atkins v. Secretary of Health and Human Services* (No. 20-333V).

on January 2, 2019, from his primary care physician, Dr. Stephen Karem, MD. Ex. 11 at 27. Petitioner reported a lump on his right arm where he received the vaccination, noting it was painful and had been lanced by his wife. *Id.* Dr. Karem diagnosed Mr. Williams with an abscess, and he incised the abscess and sent the drainage for cultures. *Id.* at 20. Dr. Karem also directed Petitioner to follow up with him later that month.

The follow-up visit with Dr. Karem occurred on January 30, 2019. Ex. 11 at 41-43. At this time, Dr. Karem observed the presence of nodule on Petitioner's right shoulder, although it was found not to be warm or tender. *Id.* at 43. A month later, Petitioner saw Dr. Karam a third time, on February 26, 2019. *Id.* at 11. Notes from this visit state that "Patient's right arm is better," but that he was "still on medication for the mycobacteremia." *Id.* A follow-up visit was scheduled for late April, but no other treatment notes pertain to the abscess. *Id.* at 14.

Petitioner subsequently had a number of other visits between March and May 2019 with Dr. Karam for unrelated concerns. *See, e.g.*, Ex. 11 at 58-63. But no mention was made of the abscess or any additional treatment specific to it.

No other medical record evidence for the period thereafter has been filed. Petitioner did, however, offer a second, single-paged affidavit in December 2024. ECF No. 21-1. In it, he represents that his abscess "remained painful and sensitive to the touch through May, 2019," and also that he felt fatigued in this period (although he seems to attribute that in part to a cardiac catheterization procedure he underwent that spring). *Id.*

III. Parties' Arguments

Petitioner claims that he experienced residual effects and/or complications for more than six months after the administration of the vaccine. Br. at 4. In support, he notes that the last medical record of his treatment is from late February 2019 – approximately four and one-half months after vaccination. *Id.* But the lack of treatment thereafter does not preclude a finding of severity. Rather, he has reported continued pain, and any such pain intermingled or exacerbated pain he was also then experiencing due to his other medical concerns. *Id.*

Respondent maintains that Petitioner has not satisfied the statutory "severity" requirement for his alleged vaccine injury. Opp. at 1. Respondent acknowledges that Petitioner attempts to allege that his injury persisted for more than six months in his more recent affidavit, but argues that this does nothing to advance his claim. *Id.* at 2. In support, Respondent cites *Hanna v. Sec'y of Health and Hum. Servs.*, No. 18-1455V, 2021 WL 3486248, at *11 (Fed. Cl. Spec. Mstr. July 15, 2021), which states that affidavits "specifically drafted for use in prosecution of petitioner's claim" are less reliable than "[c]ontemporaneous records prepared independently of litigation."

And this affidavit is not compelling evidence for a finding of ongoing severity, uncorroborated by medical record proof of Petitioner's continued treatment. Opp. at 3.

IV. Statutory Severity Requirement

A Vaccine Program petitioner carries the burden of establishing the matters required in the petition by a preponderance of the evidence. Section 13(a)(1)(A). One such requirement is "documentation demonstrating severity – generally, that the petitioner "suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." Section 11(c)(1)(D)(i)9; *see also Black v. Sec'y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the "potential petitioner" must not only make a prima facie case, but clear a jurisdictional threshold, by "submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case"), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Congress has stated that the severity requirement was designed "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied*, 132 S.Ct. 1908 (2012); *Wright v. Sec'y of Health & Human Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

The Act prohibits finding a petition requirement "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Medical records must be considered, *see* Section 13(b)(1), and are generally afforded substantial weight. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

Given the foregoing, it is indisputable that factual matters required to prove elements of a Vaccine Act claim may be established by a mix of witness statements and record proof, with the special master required to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184 (2013) (citing Section 12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

ANALYSIS

It is indisputable that there is no record evidence filed in this case establishing treatment for the Petitioner's abscess beyond four and one-half months post-vaccination. To fill this evidentiary hole, Petitioner cites to his affidavit, which was filed six years after he received the vaccine. *See generally* ECF No. 21-1. But as the Vaccine Act makes clear, "a special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1); *see also Lett v. Sec'y of Health and Hum. Servs.*, 39 Fed. Cl. 259, 260 (1997) ("Ultimately, the petitioner must substantiate the occurrence of a compensable, vaccine-related injury with independent evidence"). And as I have discussed above, the record does not corroborate Petitioner's claims of lingering pain and discomfort. I find that the affidavit should be afforded less weight than the records themselves – which suggest Petitioner's abscess had largely resolved well before six months after onset.⁴ Severity is therefore not established in this case.

CONCLUSION

Because Petitioner has failed to meet the severity requirement, his claim is dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.⁵

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

⁴ The short-term duration for this kind of vaccine-associated injury is often observed in comparable Program cases. *See e.g., Amorella-Moore v. Sec'y of Health & Hum. Servs.*, No. 91-1558V, 1992 WL 182194, at *1 (Fed. Cl. Spec. Mstr. July 13, 1992) (child who developed an abscess after a DPT vaccination received treatment and was discharged with only a small scar, 17 days post-vaccination). Indeed, even when severity *is* met in such circumstances, the relatively minor nature of a vaccination-caused abscess typically results in extremely modest damages -reflecting the inherently self-limiting nature of the injury. *See e.g., Amorella-Moore*, 1992 WL 182194, at *1 (\$500 in pain and suffering awarded, given lack of evidence of ongoing impact from abscess injury); *compare Yost v. Sec'y of Health & Hum. Servs.*, No. 18-288V, 2022 WL 4593029 (Fed. Cl. Spec. Mstr. Aug. 29, 2022) (\$10,000.00 in pain and suffering for an abscess and scarring at vaccination situs).

⁵ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.